Exhibit 24

AUROBINDO

Date: December 20, 2018

NOTIFICATION

To,

Aurolife Pharma LLC,
Dayton, NJ-08810

Subject: Evaluation of N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) impurities in Valsartan USP (Process II) manufactured by Aurobindo Pharma Limited.

Dear Customer,

We, Aurobindo Pharma Limited, Unit XI, Survey No: 61-66, IDA, Pydibhimavaram, Ranasthalam (M), Srikakulam (Dist)-532409.A.P, INDIA, hereby declare that, ***VALSARTAN USP (PROCESS II)*** is manufactured according to the process described in the **DMF # 024544.**

In connection to the US FDA query of angiotensin receptor blockers class ('sartans') and the potential risk for the contamination of these active substances with N-nitrosodimethylamine (NDMA).

Aurobindo manufacturing process does not consists of either N, N-Dimethylformamide or Triethylamine solvent during the formation of tetrazole group. Our Valsartan manufacturing process make use of Toluene as alternative solvent hence as per Chemistry the formation of N-Nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) impurities is not possible in our Synthetic Route.

However, as per EMA advice all Marketing Authorisation Holders of products containing 'sartan' APIs are being requested to implement additional testing of APIs as a precautionary measure. Taking this advice a test and control for NDMA and NDEA impurities have been included as part of the specification and test procedure of Valsartan Process II.

Test	Specification (µg/g)	Limit of Detection (µg/g)	Limit of Quantitation (µg/g)
N-Nitrosodimethylamine Content (By LCMS, µg/g)	Not more than 0.300	0.053	0.106
N-Nitrosodiethylamine Content (By LCMS, µg/g)	Not more than 0.083	0.014	0.028

Unit XI : 1/22,2/1 to 5,6 to 18, 61 to 69. IDA, Pydibhimavaram, Ranasthalam (Mandal), Srikakulam District - 532 409., A.P., INDIA Tel : ++91 8942 288 331/ 332 / 334 / 292 Fax : ++91 8942 288 293

Corp off.: The Water Mark Building, Plot No. 11, Survey No.9, Hi-tech City, Kondapur, Hyderabad - 500 084 T.S., INDIA Tel : +91 40 6672 5000 / 1200 Fax : +91 40 6707 4059

www.aurobindo.com

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Based on EMA advice we have evaluated potential impact for the presence of nitrosamine impurities in Valsartan USP (Process II). As on date 12 batches were tested for both NDMA and NDEA impurities. NDMA impurity observed "Not Detected (ND)" in all batches, however NDEA impurity observed 1 batch not detected, 2 batches Below Limit of Quantification (BLQ), 8 batches between BLQ and within specification limit and 1 batch was above the limit for batches supplied to M/s. Aurolife Pharma LLC. The details of 1 batch was above the limit are given below:

In-house Batch	Commercial Batch	Dispatch Date	Dispatched Qty. (Kg)	N-Nitroso dimethylamine (NDMA) µg/g	N-Nitroso diethylamine (NDEA) µg/g
1811105562	1811107894	31-Mar-2018	248.19	Not Detected	0.146

Further batches are under analysis for NDEA content, and we would keep posted about any additional findings immediately.

We have investigated the root cause for the carryover of N-nitrosodiethylamine (NDEA) impurities in Valsartan (Process-II) is due to Recovered Tri N Butyl Tin Chloride manufactured at contract manufacturing unit 'Lantech Pharmaceutical Ltd'. The equipment used for product distillation is common for Tri N Butyl tin chloride recovery for different organizations. The residue which is left over after the final distillation may not be completely removed as heat exchangers are not considered for cleaning between the streams of different Organizations (Which recently recalled by Mylan for Valsartan Batches due to the presence of Higher level of NDEA) during the Vacuum distillation of the Tri N Butyl Tin Chloride recovery. The carryover is attributed to inadequate cleaning procedures which led to detection of NDEA impurity in Aurobindo Valsartan API samples.

Quality Risk assessment performed and immediately discontinued the usage of recovered Tri-N-butyl chloride and as well as discontinued the manufacturing of recovered Tri-N-butyl chloride at CMU facility in the Valsartan (Process II) manufacturing process.

Kindly evaluate further Risk assessment to Drug product used by using above API lots and revert if any.

The above details is for your information and necessary action.

For AUROBINDO PHARMA LIMITED

Sarath 20/12/2018

Sarath kumar Kamavarapu
Sr. General Manager
Quality Assurance

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